

Chapter 4 -- Documents/Records

Overview Documents that provide guidance on performing activities that could significantly affect the environment, safety, and health of people and the quality of the Laboratory's operations and records that are instrumental in group operations require a system for their controlled retention and distribution.

BUS Division has formalized a Records Management and Document Control (RMDC) process that provides assistance to participating groups in identifying documents and records to be controlled, establishing document/record tracking, and providing document/record accessibility to users in a manner that meets federal, University of California, and other applicable RMDC requirements.

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Section 1 -- Records Management and Document Control Process

Overview

Introduction	Individual group participation in the RMDC process is highly recommended, but completely voluntary. This section is provided as guidance to participating BUS organizations on how to develop, implement, and maintain an RMDC system.
Definition: controlled record/ document station	<u>Controlled record/document station</u> is the designated location where controlled documents/records may be maintained by a participating group.
Definition: controlled records/ documents	<u>Controlled records/documents</u> are selected records/documents that are instrumental in group operations and/or provide guidance and are subject to revision. As such, they must be controlled to ensure controlled access and to ensure that only the latest revisions are used in activities affecting safety and quality.
Definition: document/ record control	<u>Document/record control</u> refers to the set of the planned and systematic actions necessary to provide confidence that records/documents, including changes, are retained, reviewed, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.
Definition: Division RMDC Coordinator	The <u>Division RMDC Coordinator</u> is the appointed or designated individual within the Division who is charged with assisting participating organizations in ensuring that RMDC-related activities are implemented according to established procedures.

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Overview, Continued

Definition:
group RMDC
point of contact A group RMDC point of contact is an individual designated by a participating group to represent them in RMDC activities and to serve as the liaison with the Division RMDC coordinator.

Definition:
records
management/
document
control Records management/document control is the systematic control of all selected records from their receipt/creation through their processing, distribution, organization, storage, and retrieval to their ultimate disposition.

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Responsibilities in Records Management and Document Control

BUS Division Office	BUS Division Office is responsible for the implementation of an integrated, Division-wide RMDC system.
Participating organization's management	<p>The participating organization's management should</p> <ul style="list-style-type: none">• Determine the extent of their participation in the RMDC process;• Designate an RMDC point of contact for the group;• Develop any site-specific RMDC procedures, using this document as guidance; and• Provide training to personnel involved in activities related to document control.
Division RMDC Coordinator	<p>The Division RMDC Coordinator is responsible for</p> <ul style="list-style-type: none">• Representing the Division in all RMDC activities;• Ensuring compliance with Laboratory Administrative Requirements on RMDC;• Successfully completing the Laboratory's RMDC coordinator's training;• Ensuring that designated RMDC personnel are appropriately trained;• Serving as a primary point of contact to the Laboratory RMDC Program Office;• Providing assistance in identifying controlled records/documents for the Division; and• Developing and implementing site-specific RMDC procedures according to the guidelines established by the Laboratory RMDC Program Office.
Group RMDC point of contact	Each participating organization designates a point of contact for the group who is responsible for ensuring that the RMDC process is maintained within the organization.

RMDC Procedures

Introduction Document development and record/document control is crucial in maintaining and improving processes associated with BUS Division's work activities.

Procedure Follow the steps below to develop and control a new or revised document.

Step	Who Does It	Action
1	Group management	<ul style="list-style-type: none">• Determine which documents will be controlled;• Determine that a new document will be developed or that an existing one needs to be revised and• Task the appropriate employee with drafting/revising the document. <p><u>Note:</u> All participating personnel may obtain assistance from the Division RMDC Coordinator, as needed.</p>
2	Document owner	<ul style="list-style-type: none">• Gather data and draft/revise the document and• Submit the document to group management for approval.
3	Group management	<ul style="list-style-type: none">• Approve the draft new/revised document and• Return the document to the document owner.
4	Document owner	<ul style="list-style-type: none">• Submit the document to the group's RMDC point of contact (one hard copy and one diskette copy).
5	RMDC point of contact	<ul style="list-style-type: none">• Assign a number, if the document is new, and date it;• Copy the document to the master electronic file and delete the existing one, as applicable;• Update the master index;• Print a master copy of the document and the index and place both copies in the group master file in sequential order;• Delete the existing procedure and index, if the document is being revised; and• Copy the document and index and submit them to group management for further action.

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RMDC Procedures, Continued

Records management procedure

Follow the steps below to develop and control a new or revised document.

Step	Who Does It	Action
1	Group management	<ul style="list-style-type: none">• Determine that a record needs to be controlled and• Assign ownership of the record to the appropriate employee. <p><u>Note:</u> All participating personnel may obtain assistance from the Division RMDC Coordinator, as needed.</p>
2	Document owner	<ul style="list-style-type: none">• Submit the record to the group's RMDC point of contact.
3	RMDC point of contact	<ul style="list-style-type: none">• Assign an identifier, for filing purposes and date the record;• Copy the record to the master electronic file, if applicable;• Update the master index and delete the previous version; and• Maintain a master copy of the index and the record in the group master file in sequential order.

Record/document retention

Records/documents are to be reviewed and retained as determined by group management.

Self-assessment

RMDC process performance is to be included as part of the annual BUS Division management assessment.
